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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,815	04/13/2001	Barnett S. Pitzele	PHAR 7978/3312US	8682

7590 04/17/2002

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St. Louis, MO 63167

EXAMINER

ZUCKER, PAUL A

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 04/17/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/834,815

Applicant(s)

Examiner

Paul A. Zucker

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement filed 06 August 2001 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy each non-patent publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The initialed items (US Patent, WO and EP documents) on the information disclosure statement have been considered. The non-patent literature referred to therein has not been considered. Applicant is invited to forward copies of the relevant references directly to the examiner for timely consideration.

### ***Specification***

2. The abstract of the disclosure is objected to because the abstract should indicate to the reader what contribution to the art is represented by the invention. The current abstract only indicates the general field of the invention. A revised abstract on a separate page are required. Correction is required. See MPEP § 608.01(b).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

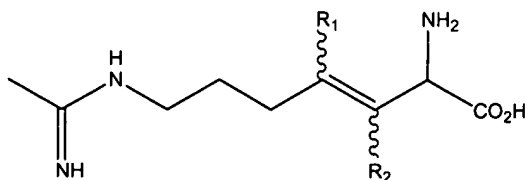
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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

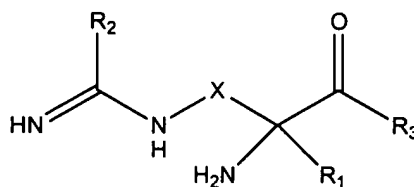
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Currie et al (WO 95/25717-A1 10-1995) and further in view of Hallinan et al (US 6,344,483 02-2002).

The invention is directed toward the compounds (geometric and stereoisomers) of Formula (I), where  $R_1$  and  $R_2$  may be H or methyl, or their pharmaceutically acceptable salts :



Currie generically discloses (Page 4, line 1-page 5, line 10) a genus of nitric oxide synthase inhibitors of general formula (I):



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Where  $R_3$  may be hydroxyl,  $R_2$  may be methyl and  $R_1$  may be hydrogen or lower alkyl (methyl). A preferred embodiment of the compounds is further taught (Page 7 line 9-21) where X= lower alkenyl, lower alkynyl, where lower denotes 1-6 carbons. Currie further teaches (Page 7, lines 27-30) alkyl substitution of the alkenyl and alkynyl core.

Hallinan teaches (Column 3, line 24 - column 4, line 48) nitric oxide synthase inhibitors closely related in structure to Currie's and refers (Column 3, line 3) to Currie's disclosure directly. Hallinan further discloses alkenyl (Column 18, line 1 - column 19, line 2) and alkynyl (Column 19, line 3- column 20, line 27) amidino amino acids.

Hallinan's disclosure and teachings provide the motivation for one of ordinary skill in the art to actually synthesize the alkenyl and alkynyl compounds taught by Currie.

Thus the instantly claimed compounds would have been obvious for one of ordinary skill in the art. The motivation for combination of the two references is provided by the reference by Hallinan to Currie as well as the common field of invention. The expectation for success would have been near certitude since Currie's genus completely embraces the instant compounds which, Currie teaches, have the instantly desired activity as nitric oxide synthase inhibitors.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

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harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

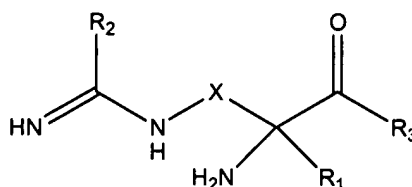
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

This is a provisional obviousness-type double patenting rejection.

4. Claims 1-28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-202 of copending Application No. 09/952,888 in view of Currie et al (WO 95/25717-A1 10-1995).

Currie generically discloses (Page 4, line 1-page 5, line 10) a genus of nitric oxide synthase inhibitors of general formula (I):



Where R<sub>3</sub> may be hydroxyl, R<sub>2</sub> may be methyl and R<sub>1</sub> may be hydrogen or lower alkyl (methyl). A preferred embodiment of the compounds is further taught (Page 7 line 9-21) where X= lower alkenyl, lower alkynyl, where lower denotes 1-6 carbons. Currie further teaches (Page 7, lines 27-30) alkyl and halo substitution of the alkenyl and alkynyl core.

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Instant claims 1-28 are drawn to compounds that differ in structure from those of claims 1-202 of copending Application No. 09/952,888 only by the fact that a single methyl group has been deleted from the amino acid alpha carbon. The instant compounds are thus *prima facie* obvious over those of 09/952,888 since they would be an expectation by one of ordinary skill in the art that they would have similar utility.

The following are examples of the correspondence of claims within the two applications.

Instant Claim Number	09/952,888 Claim Number
3	12
6	19
11	79
15	88

In the instant case this obviousness is reinforced by the common membership in the genus of Currie of the instant compounds and those of 09/952,888.

### ***Conclusion***

5. Claims 1-28 are outstanding. Claims 1-28 are rejected.
6. The following art, not relied upon for rejections in this action, is considered pertinent to Applicant's disclosure:

Beams et al, US 5,863,931 01-1999:

Discloses a genus of compounds embracing the instantly claimed compounds.

Whitten et al, EP 0 446 699 A1 09-1991:

Discloses vinyl-substituted amino acids for nitric oxide synthase type activity.

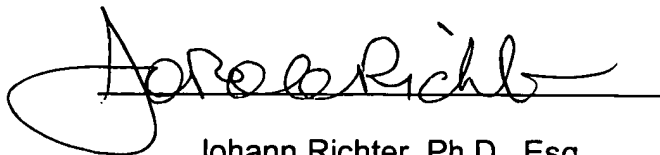
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 703-306-0512. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 703-308-4532. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Paul A. Zucker  
Patent Examiner  
Technology Center 1600

April 17, 2002

A handwritten signature in black ink, appearing to read 'Johann Richter', with a large, stylized initial 'J' and a horizontal line extending to the right.

Johann Richter, Ph.D., Esq.  
Supervisory Patent Examiner  
Technology Center 1600